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09/942,336	08/29/2001	Tetsuo Ashizawa	HO-P02039US1	7107

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EXAMINER

STRZELECKA, TERESA E

ART UNIT PAPER NUMBER

1637

DATE MAILED: 07/23/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,336

Applicant(s)

ASHIZAWA ET AL.

Examiner

Teresa E Strzelecka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 18-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 10 and 14-17 is/are rejected.
- 7) ☒ Claim(s) 8 and 11-13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. This office action is in response to an amendment filed on October 1, 2002. Claims 1-28 were pending, with claims 18-28 withdrawn from consideration. Applicants' amendments of claims 1, 5, 8, 14, 16 and 17 render moot the rejection of claims 1-17 under 35 U.S.C. 112, 2nd paragraph. Claims 1-17 will be examined.
2. The original response to an office action of July 3, 2002 was found and it was placed in the case.

Information Disclosure Statement

3. The information disclosure statement filed October 1, 2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because a) references CK and CL are citations from internet sites, which change in time, therefore these citations do not have a proper place and date of publication. Citation CZ is a copy of CO. It has been placed in the application file, but the information referred to in CK and CL has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 C(1).
4. Documents CW, CX and DA were missing from the IDS. After telephone call to Melissa Sistrunk on July 15, they were faxed to the office. However, the documents faxed are submission s of abstracts for these publications, not the actual publications. They were considered as abstract submissions.
5. This office action is made non-final because of new grounds for rejection.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 4, 5, 7, 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 4 recites the limitation "the amplification" in line 1. There is insufficient antecedent basis for this limitation in the claim.

B) Claim 5 recites the limitation "the primers" in line 1. There is insufficient antecedent basis for this limitation in the claim.

C) Claim 7 recites the limitation "the restriction enzyme" in line 1. There is insufficient antecedent basis for this limitation in the claim.

D) Claims 14 and 15 are indefinite in claim 14, because claim 14 does not recite a final process step which clearly relates back to the preamble. The preamble states that the method is for detecting pentanucleotide repeats in SCA10, but the final process step is performing PCR using primers of the sequence consisting of SEQ ID NO: 3 and SEQ ID NO: 4. Therefore, it is unclear as to whether the claim is intended to be limited to a method of detecting pentanucleotide repeats in SCA10 or a method of performing PCR using primers of the sequence consisting of SEQ ID NO: 3 and SEQ ID NO: 4. Therefore, claim 14 is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: detection of pentanucleotide repeats.

E) Claim 16 is indefinite because the claim does not recite a final process step which clearly relates back to the preamble. The preamble states that the method is for diagnosing spinocerebellar

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ataxia type 10, but the final process step is determining whether the number of ATTCT repeats is expanded. Therefore, it is unclear as to whether the claim is intended to be limited to a method of diagnosing spinocerebellar ataxia type 10 or a method of determining whether the number of ATTCT repeats is expanded. Therefore, claim 16 is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: diagnosing spinocerebellar ataxia type 10.

F) Claim 17 is indefinite because the claim does not recite a final process step which clearly relates back to the preamble. The preamble states that the method is for diagnosing spinocerebellar ataxia type 10, but the final process step is determining whether the number of ATTCT repeats is expanded. Therefore, it is unclear as to whether the claim is intended to be limited to a method of diagnosing spinocerebellar ataxia type 10 or a method of determining whether the number of ATTCT repeats is expanded. Therefore, claim 17 is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: diagnosing spinocerebellar ataxia type 10.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Matsuura et al. (Ann. Neurol., vol. 46, pp. 480-1, September 1999 ; cited in the IDS).

Matsuura et al. teach detection of DNA expansion due to CAG repeats at a gene locus of spinocerebellar ataxia type 10 (SCA10) gene locus (page 480, 481).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 2-4, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuura et al. (Ann. Neurol., vol. 46, pp. 480-1, September 1999; cited in the IDS) and Koob et al. (Nature Genetics, vol. 21, pp. 379-384, April 1999; cited in the IDS).

A) Matsuura et al. do not teach expansion detection by PCR or Southern blotting.

B) Regarding claims 2 and 4, Koob et al. teach detection of trinucleotide repeat expansion by PCR with primers specific for ataxia gene locus. Genomic DNA samples were amplified with locus-specific primers and the presence of the expansions was determined (page 383, 8th full paragraph; page 380, third paragraph). Koob et al. do not specifically teach DNA extraction, but they teach amplification of isolated genomic DNA, which means that the DNA was extracted from samples.

Regarding claims 6 and 7, Koob et al. teach detection of large expansion alleles by Southern blotting on EcoRI digested genomic DNA (page 383, 8th full paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to apply the methodology of Koob et al. (PCR plus Southern blotting) to the detection of DNA expansion in the SCA10 locus. The motivation to do so, provided by Koob et al., would have been that PCR gave accurate sizing of the expanded repeats and Southern blotting detected expansion alleles longer than 200 repeats (Fig. 3; page 383, 8th full paragraph).

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12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuura et al. (Ann. Neurol., vol. 46, pp. 480-1, September 1999; cited in the IDS) and Del-Favero et al. (Hum. Genet., vol. 105, pp. 217-225, September 1999).

A) Matsuura et al. do not teach expansion detection using pulsed field gel electrophoresis (PFGE).

B) Del-Favero et al. teach isolation and analysis of trinucleotide repeats using YAC (yeast artificial chromosome fragmentation (Fig. 1). YACs were separated according to size by PFGE (page 219, first full paragraph; Fig. 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the PFGE-based method of Del-Favero et al. to detect DNA expansion of Matsuura et al. The motivation to do so, provided by Del-Favero et al., would have been that using YACs allowed isolation and mapping of repeats to defined regions on the chromosome (Abstract).

13. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuura et al. (Ann. Neurol., vol. 46, pp. 480-1, September 1999; cited in the IDS) and Haaf et al. (Nature Genet., vol. 12, pp. 183-185, 1996).

A) Matsuura et al. do not teach expansion detection using fluorescence in situ hybridization (FISH).

B) Haaf et al. teach detection of expanded trinucleotide repeats by FISH (Fig. 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the FISH method of Del-Favero et al. to detect DNA expansion of Matsuura et al. The motivation to do so, provided by Haaf et al., would have been that using FISH enabled rapid localization of expanded repeats on chromosomes (page 183, first paragraph).

Allowable Subject Matter

14. No references were found teaching or suggesting claims 5, 8, 11-17.
15. Claims 8, 11-13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
16. Claims 14-17 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.
17. Claim 5 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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July 21, 2003

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BJ FORMAN, PH.D.
PRIMARY EXAMINER